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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/570,047 | 04/16/2007 | Rolf Jessberger | 29636/39363A | 8165 |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 | | | EXAMINER | |
| | | | SHIN, DANA H | |
| SEARS TOWER CHICAGO, IL 60606 | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/29/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|---|--|--|--|--|--|--|
| Office Action Commence | 10/570,047 | JESSBERGER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Dana Shin | 1635 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | l. lely filed the mailing date of this communication. (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>31 Oc</u> | otober 2007 | | | | | |
| | | | | | | |
| <i>i</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| · · | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) X Claim(s) 1 2 10-19 29-32 34-44 48 49 134 139 | and 140 is/are nending in the an | nlication | | | | |
| 4)⊠ Claim(s) <u>1,2,10-19,29-32,34-44,48,49,134,139 and 140</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | · · · · · · · · · · · · · · · · · · · | | | | | |
| 7) Claim(s) is/are rejected. | | | | | | |
| · | and 140 are subject to restriction | and/or election requirement | | | | |
| 8)⊠ Claim(s) <u>1,2,10-19,29-32,34-44,48,49,134,139 and 140</u> are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | te | | | | |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 10-19, 29-32, 34-44, 48-49, and 134, drawn to a method of inducing infertility in an animal comprising administering an antisense oligonucleotide that inhibits SMC1 β , which is SEQ ID NO:1 or SEQ ID NO:3.

Group II, claim(s) 1, 10-32, 34-43, 48-49, and 134, drawn to a method of inducing infertility in an animal comprising administering a small molecule antagonist of SMC1β.

Group III, claim(s) 1, 10-32, 34-43, 48-49, and 134, drawn to a method of inducing infertility in an animal comprising administering a peptidomimetic antagonist of SMC1β.

Group IV, claim(s) 1, 10-32, 34-43, 48-49, and 134, drawn to a method of inducing infertility in an animal comprising administering an anti-SMC1β antibody.

Group V, claim(s) 139, drawn to a method of diagnosing a disorder in an animal comprising determining the amount of SMC1 β in a sample.

Group VI, claim(s) 140, drawn to a composition comprising an agent that induces SMC1β expression and a pharmaceutically acceptable carrier.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

In view of 37 CFR 1.475 (b) and 37 CFR 1.475 (c), unity of invention is not present in the claims of the instant application because multiple processes and different categories of invention are claimed in the instant application.

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Furthermore, according to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed antitumor agents, the Marksuh group shall be regarded as being of similar nature when

- (A) all alternatives have a common property or activity and
- (B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

In the instant application, claim 17 contains a Markush-type claim language: "wherein said agent is selected from the group consisting of: a nucleic acid construct, a small molecule antagonist of SMC1β, a peptidomimetic antagonist of SMC1β, and an anti-SMC1β antibody". The claimed agents are considered to be each separate invention for the following reasons:

The agents do not meet the criteria of (A) and (B)(1), because there is no common structure shared by all of the alternatives (e.g., compare a nucleic acid construct having nucleotides with an antibody having amino acids) and there is no common property shared by all of the alternatives (e.g., compare DNA/RNA-binding nucleic acid construct with peptide-binding antibody). Accordingly, unity of invention among the agents is lacking and each agent claimed is considered to constitute a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin Examiner Art Unit 1635

> /J. E. Angell/ Primary Examiner, Art Unit 1635